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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/622,094 10/17/00 DUIRS

G 08059.0004

EXAMINER

HM12/0717

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DEWITTY, R

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/622,094

Applicant(s)

DUIRS, GRAHAM FRANCOIS

Examiner

Robert M DeWitty

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30/11/00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

Claims 1-10 are pending in the instant application.

#### ***Claim Objections***

1. Claims 4-8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependent from a multiple dependent claim. See MPEP § 608.01(n). Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Specifically, the drawings of the substance delivery device cannot be practiced by one with ordinary skill in the art.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim is limited to the description of the

method of delivering drugs contained in the specification, however the specification contains different variations, including preferred methods. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fournier.

Fournier (U.S. Pat. No. 3,818,911) teaches applicators for liquid or semi-solid Compositions. The applicators may be used for purposes including applying medicated compositions to internal body surfaces (col. 1, lines 44-47). One such embodiment of the invention is adapted for feminine hygiene purposes (col. 3, lines 57-64). The applicator (vaginal) is fashioned so that it includes (1) a grippable base member, (2) a elongated support member, and (3) a continuous layer of cured polymeric foam material (col. 4, lines 41-50). The base member may be so constructed so that it can be detached and reused as a holder for fully disposable applicator tips which comprise the polymeric foam layer (col. 4, lines 58-62). [In some embodiments, the polymeric foam is provided with annular convoluted folds which extend downwardly to increase the surface area (col. 5, lines 39-43)] The vaginal applicator can be supplied with preimpregnated therapeutic and non-therapeutic compositions (col. 5, lines 4-6).

Fournier also points out that the prior art teaches vaginal applicators comprised of rubber, finger-like projections, however this applicator is intended for douching and does not have a capping means (col. 1, lines 16-21).

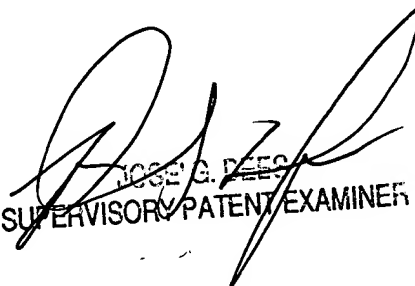
Thus, the instant invention is anticipated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
July 16, 2001

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616